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10/068,559	02/05/2002	C. Grant Willson	5119-07301	6950

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ERIC B. MEYERTONS
CONLEY, ROSE & TAYON, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,559

Applicant(s)

WILLSON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50, 76 and 98-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50, 76, 98-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 50, 76 and 98-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al.(US 6,327,410) in view of Felder et al.(US 6,232,066), Chang et al.(US 6,350,620) or Ravkin et al.(US 2003/0008323).

The reference of Walt et al. discloses a method of sensing multiple analytes in a fluid that includes passing a fluid over a sensor array wherein the sensor array includes a plurality of sensing elements coupled to a supporting member, wherein a first portion of the sensing elements are configured to produce a signal in the presence of a first analyte and wherein a second portion of the sensing elements are configured to produce a signal in the presence of a second analyte. The first and second portions of the sensing elements have unique predetermined optical signatures or tags wherein the optical signature or tag of the first portion of sensing elements is different from the optical signature or tag of the second portion of sensing elements. The method includes monitoring a spectroscopic change of the sensing elements as the fluid is passed over the sensing array, wherein the spectroscopic change is caused by the interaction of the analyte with the sensing element and determining the unique optical signature of the sensing elements that undergo a spectroscopic change (See column 13, lines 8-24, and column 15, line 64, to column 16, line 20).

With respect to claim 76, while the reference of Walt et al. disclose the use of unique predetermined optical signatures or tags that include the use of beads of different size (See column 18, lines 48-58, and column 19, lines 6-13), claim 76 differs by reciting that the method employs sensing elements (beads) of different shapes wherein the sensing element undergoing a spectroscopic change is identified by its shape.

The reference of Felder et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 8, lines 49-56).

The reference of Chang et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See column 3, lines 33-39).

The reference of Ravkin et al. discloses that it is known in the art to provide analyte detection beads with unique optical signatures or tags wherein the beads can be of different size or shape (See paragraphs [0096], [0137] and [0139]).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a unique optical signature with respect to the beads of the primary reference of Walt et al. using beads of different shapes for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a means for optically distinguishing one sensing element from another. Use of beads of different shape rather than size would eliminate the need to employ different sized optical fibers required to detect the beads of different size. The same types of optical fibers would be capable of detecting beads of similar size but different shapes.

With respect to claim 109, the sensing elements comprise a polymer (See column 7, lines 20-41).

With respect to claim 110, the reference of Walt et al. discloses that the sensing elements can be made of polyethylene glycol hydrogel (See column 18, lines 3-20).

With respect to claims 111-118, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte. The reference also discloses a number of methods for attachment of the receptor to the sensing element. The reference stresses that the method of attachment should not alter the functionality of the bioactive agent (See column 7, line 55, to column 12, line 62).

With respect to claim 50, the reference of Walt et al. discloses that immobilization of the different sensing elements to substrate (212) to form a sensing array includes placing the sensing elements in a liquid composition and curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claims 98 and 100, the reference of Walt et al. discloses that the sensing elements can be made from a polymer (See column 7, lines 20-41).

With respect to claim 99, the sensing elements are placed near the surface of the liquid composition (See column 17, line 47, to column 18, line 2).

With respect to claim 101, the reference of Walt et al. discloses that the sensing elements can be made of polyethylene glycol hydrogel (See column 18, lines 3-20).

With respect to claims 102-108, the reference of Walt et al. discloses a number of receptors that can be used and produce a signal when they interact with an analyte. The

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reference also discloses a number of method for attachment of the receptor to the sensing element. The reference stresses that the method of attachment should not alter the functionality of the bioactive agent (See column 7, line 55, to column 12, line 62).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 76 and 109-118 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 117-143 of copending Application No. 10/832,469 in view of Walt et al.(US 6,327,410).

Claims 117-143 of copending 10/832,469 encompass a method that is substantially the same as that instantly claimed. Any of the minor differences between the instant claims that are not encompassed by the limitations of copending claims 117-143 would have been obvious in view of the reference of Walt et al. for the same reasons as set forth in the 35 USC 103 rejection set forth above.

5. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

6. With respect to the rejection of claim 50 under 35 USC 103 over the combination of the references of Walt et al. and Felder et al., Applicants argue (See pages 7-11 of the response filed 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in combination with the reference of Felder does not teach or suggest “curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition”.

In response, Applicants’ comments are not found to be persuasive because the Examiner is of the position that particles that are held within the cavities of the substrate by a polymer composition meet the instant claim language. That is, the polymer composition that is employed to hold the particles within the cavities constitutes a supporting member and since the particles are coupled to the substrate cavities using the polymer, the particles must be “at least partially embedded” in the polymer composition that is cured, if not, they would not be capable of being held in the cavities. Note the reference of Felder et al. was not relied upon to address this specific claim limitation. The reference of Felder et al. was relied upon to address the use of particles of different shapes.

7. With respect to the rejection of claim 76 under 35 USC 103 over the combination of the references of Walt et al. and Felder et al., Applicants argue (See pages 11-12 of the response dated 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in combination with the reference of Felder does not teach or suggest “determining the shape of the

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sensing elements that undergo a spectroscopic change”. Applicants stress that the reference of Felder et al. **appears** to teach that the shape of the surface that the anchors are associated with is not critical.

In response, Applicants’ comments are not found to be persuasive for the following reasons. Applicants’ reference to the text of Felder et al. has been taken out of context. Column 5, lines 14-15, is related to the shape of the support surface or member in which the regions of anchors can be associated with. Applicants’ comments are completely silent with respect to the disclosure of Felder et al. at column 8, lines 39-61. This part of the disclosure clearly conveys to one of ordinary skill in the art that particles of different shapes can be used as labels for different anchor regions on a substrate such that the detection areas on the substrate assume a random position within the test region. Use of labels of different shapes requires a step of determining the shape of the label so as to determine which anchor region has undergone a spectroscopic change in response to exposure to a test sample.

8. With respect to the rejection of claim 50 under 35 USC 103 over the combination of the references of Walt et al. and Chang et al., Applicants argue (See pages 12-13 of the response filed 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in combination with the reference of Chang et al. does not teach or suggest “curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition”.

In response, Applicants’ comments are not found to be persuasive because the Examiner is of the position that particles that are held within the cavities of the substrate by a polymer

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composition meet the instant claim language. That is, the polymer composition that is employed to hold the particles within the cavities constitutes a supporting member and since the particles are coupled to the substrate cavities using the polymer, the particles must be “at least partially embedded” in the polymer composition, if not, they would not be capable of being held in the cavities. Note the reference of Chang et al. was not relied upon to address this specific claim limitation. The reference of Chang et al. was relied upon to address the use of particles of different shapes.

9. With respect to the rejection of claim 76 under 35 USC 103 over the combination of the references of Walt et al. and Chang et al., Applicants argue (See pages 13-14 of the response dated 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in combination with the reference of Chang et al. does not teach or suggest “determining the shape of the sensing elements that undergo a spectroscopic change”. Applicants stress that the reference of Chang et al. does not appear to teach or suggest the sensing element undergoing a spectroscopic change.

In response, Applicants’ comments are not found to be persuasive for the following reasons. The Examiner is of the position that the reference of Chang et al. clearly discloses the detection of a spectroscopic change. Specifically, the reference specifically recites “a signal, such as fluorescence, is obtained when the micro-carrier is complementary with or recognized by the unknown bio-molecule” (See column 3, lines 14-16). The generation of a signal which is fluorescent clearly indicates that the sensing element (micro-carrier) is undergoing a spectroscopic change. Specifically, the reference of Chang et al. further discloses that the

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signally micro-carrier is further interrogated using image recognition (bar code or shape) to determine the identity of the signally micro-carrier (See column 3, lines 17-39).

10. With respect to the rejection of claim 50 under 35 USC 103 over the combination of the references of Walt et al. and Ravkin et al., Applicants argue (See page 15 of the response dated 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in combination with the reference of Ravkin et al. does not teach or suggest “curing the liquid composition to form a supporting member, wherein the sensing elements are at least partially embedded within the cured liquid composition”.

In response, Applicants’ comments are not found to be persuasive because the Examiner is of the position that particles that are held within the cavities of the substrate by a polymer composition meet the instant claim language. That is, the polymer composition that is employed to hold the particles within the cavities constitutes a supporting member and since the particles are coupled to the substrate cavities using the polymer, the particles must be “at least partially embedded” in the polymer composition, if not, they would not be capable of being held in the cavities. Note the reference of Ravkin et al. was not relied upon to address this specific claim limitation. The reference of Ravkin et al. was relied upon to address the use of particles of different shapes.

11. With respect to the rejection of claim 76 under 35 USC 103 over the combination of the references of Walt et al. and Ravkin et al., Applicants argue (See pages 15-16 of the response dated 8/8/05) that the rejection is improper because the reference of Walt et al. alone or in

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combination with the reference of Ravkin et al. does not teach or suggest “determining the shape of the sensing elements that undergo a spectroscopic change”. Applicants stress that the reference of Ravkin et al. **appears** to teach carriers that have coded indicia and coded positions that are attached to the carriers, the indicia may be used to determine the shape of the carrier, and the geometry of the carrier may serve as the coding indicia.

In response, Applicants’ comments are not found to be persuasive for the following reasons. In view of Applicants’ admission that the reference of Ravkin et al. appears to disclose that shape can be used as a coding indicia, it is not clear how Applicants can argue that the reference of Ravkin does not appear to teach or suggest “determining the shape of the sensing element that undergo a spectroscopic change”. Note the carriers undergo a spectroscopic change as evidenced by the use of colored or fluorescent labels (See paragraph [0145]).

12. With respect to the rejection of claims 76 and 109-118 under obviousness-type double patenting over U.S. Application 10/832,469 in view of Walt et al., Applicants argue (See pages 16-17 of the response filed 8/8/05) that they disagree with the rejection but will consider filing a terminal disclaimer once the claims are indicated as being allowable.

In response, Applicants’ comments are not found to be persuasive since specific arguments have not be presented as to why they disagree and/or a terminal disclaimer has not been filed.

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13. With respect to claims 98-118, Applicants argue (See pages 17-20 of the response filed 8/8/2005) that the dependent claims are independently patentable and generically argue that the dependent claims do not appear to be taught or suggested by the cited art.

In response, the prior art rejection of record under 35 USC 103 addresses each of the dependent claim limitations, Applicants' comments fail to specifically state why the cited prior art does not teach or suggest the specific limitations of these claims.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

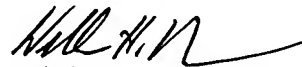
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB